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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,808	07/08/2005	Robert N Hotchkiss	OBK-001.02	6115

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EXAMINER	
MAHYERA, TRISTAN J	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,808	HOTCHKISS ET AL.	
	Examiner	Art Unit	
	TRISTAN J. MAHYERA	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/8/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-20 are pending and examined on the merits.

Priority

Applicant's claim for the benefit of PCT/US05/00999 and 60/536135 filed 1/13/2004 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7, 8, 11, 12 and 18-20 are rejected under 35 U.S.C. 102(a/e) as being anticipated by WATSON et al. (US 2003/0139811 see PTO/SB/08).

WATSON teaches a device and methods of intra-articular drug delivery comprising local administration of a sustained release device and drug. See e.g. Abstract and p[0011]. The method includes the step of affixing a drug release device in

a preselected attachment zone in a synovial joint. See e.g. p[0027]: instant claims 1 and 19. The selection of the attachment zone includes placement lateral to the origin of the posterior cruciate ligament in the anterior intercondyloid fossa, which includes the non-articulation portion of the joint that is within the synovial fluid and adjacent to the articulating surface of the condyloids. See e.g. p[0052]: instant claims 2, 5, 11, 12, 15, 19 and 20. The attachment zone further includes a band of bone, which the Examiner believes is any bone section near the articulating surface and is read on by the actual placement of the screw above: instant claims 5 and 12. The sustained release device includes a base (e.g. the screw portion) that is affixable in the attachment zone. See e.g. the bone screw of p[0069] and attachment zone within the stifle or knee joints of p[0052] and [0064]: instant claims 1, 19 and 20. The device is capable of releasing one or more drugs over an extended period of time, from about 3 months to 10 years. See e.g. p[0031] and p[0038]: instant claims 1, 19 and 20. The device has a carrier, e.g. a chamber in the head of the bone screw that releases the drug in a sustained manner or e.g. an inner core containing a matrix of an effective agent and a polymer that is permeable to the effective agent. See e.g. claims 1, 3, and 16: instant claims 1, 19 and 20. To attach the system of the embodiments shown in Figs. 2A-5 to a mammal, a void, such as a chamfered hole, is first drilled into a bone. See e.g. p[0090]: instant claims 3, 7, 18, 19 and 20. The device has threads on its outer surface and is then screwed into the void such that the head of the device is flush with the bone. See e.g. p[0090] and Fig2A-5: instant claims 4, 8, 18, 19 and 20. The drug is released into the synovial fluid, which causes the concentration of the drug to remain higher in the synovial fluid and

several orders of magnitude lower in the plasma, which reads on the drug release device is in communication with the synovial fluid or elutes the drug into the fluid of instant claims 1, 3, 7, 8, 19 and 20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6 and 9, 10, 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WATSON.

WATSON teaches a device and methods of intra-articular drug delivery comprising local administration of a sustained release device and drug, as described above.

WATSON does not explicitly teach wherein the synovial joint is a hip joint or shoulder joint or an arthroplastic joint.

WATSON does teach the bone screw can be readily adapted to a large number of orthopedic hardware components, specifically a prosthetic joint (i.e. arthroplastic joint) which can be a hip socket (Fig 17K) a knee prosthesis (Fig. 17L) and to the foot, ankle or shoulder. See e.g. p[0129]: instant claims 9, 13, 15 and 16. As stated above the band of bone is merely a portion of the bone near an articulating surface and in some embodiments defines the attachment zone.

Since WATSON teaches that the components can be placed in numerous parts of the anatomy to anchor the drug delivery device (see e.g. p[0129]), it would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine an attachment zone within 0.5mm to 1 cm from the articulating surface in claim 6 and furthermore to actually attach the screw or other device adjacent to the femoral head/acetabulum of the hip or adjacent to the anatomical neck of a humerus, a

glenoid cavity or a glenoid neck of a shoulder joint because WATSON suggests that the device can be used in a hip, knee and shoulder joint: instant claims 6, 10 and 14.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over WATSON as applied to claims 1-16 and 18-20 above, and further in view of SATER et al (US 6,893,446 see PTO-892).

SATER teaches bone anchor placement devices that are gun shaped and activated when a user force squeezes a lever. See e.g. Abstract. An advantage of the bone anchor placement devices is that they seat a self-tapping bone anchor screw with a pre-attached suture. Since the bone anchor screw used with the disclosed devices is self-tapping and the suture is pre-attached, it is unnecessary for the physician to prebore a hole into the bone, remove the drill, introduce a seating device, seat the bone anchor screw, and then thread the suture. Single-step insertion of the bone anchor screw and suture not only reduces the total time required for the procedure, it also greatly reduces the possibility that the physician may lose access to the bored hole or seated bone anchor screw. Thus, the possible need to drill additional holes and/or seat additional bone anchor screws is reduced. See e.g. col. 2 lines 3-16: instant claim 17.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a device that can be forcefully inserted into a bone by the use of a gun, as taught by WATSON in view of SATER. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single device because a single-step insertion of the bone anchor screw

and suture not only reduces the total time required for the procedure, it also greatly reduces the possibility that the physician may lose access to the bored hole or seated bone anchor screw. Thus, the possible need to drill additional holes and/or seat additional bone anchor screws is reduced, as taught by SATER. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-20 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-20 of copending Application No. 11/035375. This is a

provisional double patenting rejection since the conflicting claims have not in fact been patented.

The claims of both applications are identical in scope.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRISTAN J. MAHYERA whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Thursday 9am-7pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P. WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tristan J Mahyera/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615